United States District Court
District of Massachusetts

Iron Workers District Council of New England Health and Welfare Fund et al., *on behalf of themselves and others similarly situated*	)	
Plaintiffs,	)	**Civil Action No. 23-11131-NMG**
v.	)	
Teva Pharmaceutical Industries Ltd. et al.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

The suit arises out of allegations that defendants, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Branded Pharmaceutical Products R&D, Inc. (collectively, "Teva") and Norton (Waterford) Ltd. ("Norton" and collectively, "defendants"), have engaged in illegal, anti-competitive practices to block introduction of a generic drug which competes with its QVAR and QVAR Redihaler lines of inhaler products. Plaintiffs are health and welfare funds of labor unions representing a putative class of entities and individuals that have allegedly overpaid for prescription asthma medication as a result of the purported anti-competitive practices.

Currently pending before the Court is defendants' motion to dismiss (Docket No. 39). For the reasons that follow, the motion will be allowed, in part, and denied, in part.

I. Background

A. Regulatory Background

Plaintiffs allege that Teva has created artificial barriers to prevent generic competition with its QVAR inhaler products. Generic drugs are biologically equivalent to and yet considerably cheaper than their brand-name counterparts. See Impax Laboratories, Inc. v. FTC, 994 F.3d 484, 488 (5th Cir. 2021).

The Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, more commonly known as the Hatch-Waxman Act, incentivizes market entry of generics by streamlining the Food and Drug Administration ("FDA") approval process. To gain approval to market a new drug, drug manufacturers must submit a New Drug Application ("NDA") to the FDA and undergo a lengthy testing process. See 21 U.S.C. § 355(b)(1).

Generic drug manufacturers can, however, file an Abbreviated New Drug Application ("ANDA"), see 21 U.S.C. § 355(j), whereby the manufacturer is called upon to establish that the generic drug has the same active ingredients and is biologically equivalent to the brand drug. New York ex rel.

Schneiderman v. Actavis PLC ("Namenda"), 787 F.3d 638, 644 (2d Cir. 2015)). A generic drug is biologically equivalent to a brand drug when, under similar experimental conditions, the active ingredient is absorbed at the same rate and to the same extent. See 21 U.S.C. § 355(j)(8)(B)(i). In effect, the Hatch-Waxman Act enables generic competitors to "piggy-back on the pioneer[] [drug's] approval efforts," expediting the introduction of generic drugs. FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013).

The Hatch-Waxman Act also contains provisions for resolving patent disputes arising from the introduction of generics. FDA-approved drugs and related patent information are listed in what is colloquially known as "the Orange Book." See Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last updated Apr. 12, 2024). Drug manufacturers are not, however, allowed to list all drug-related patents in the Orange Book. Rather, the FDA requires that manufacturers list only patents that claim "the drug substance, drug product (composition / formulation), or one or more methods of using the drug for which it is listed." In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 4 (1st Cir. 2020) (internal quotations omitted); see also 21 C.F.R. §

314.5(c)(2)(i). The FDA has disclaimed monitoring the Orange Book for accuracy and drug manufacturers must declare that listed patents meet the definition in the regulation.

When a generic manufacturer submits an ANDA, it must make certifications with respect to the patents of the branded drug that are listed in the Orange Book. For the relevant patents, a generic manufacturer can certify that 1) the patent has expired, 2) the generic manufacturer will wait for the patent to expire before marketing the generic drug or 3) that the patent will not be infringed by the introduction of the generic. See 21 U.S.C. § 355(b)(2)(A)(i)-(iv). The third option is referred to as a "Paragraph IV certification." See In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d at 4.

A Paragraph IV certification compels the resolution of patent disputes before a generic drug comes to market. The filing of a Paragraph IV certification enables the patentholder (i.e. the brand drug manufacturer) to sue the generic competitor for infringement without exposing the generic competitor to potential damages. Id. If such a suit is commenced within 45 days of receipt of a Paragraph IV certification, an automatic 30-month stay of FDA approval of the generic is triggered. 21 U.S.C. § 355(c)(3)(C). The stay can be shortened by resolution of the action or by court order. Id. The first generic manufacturer to file an ANDA with a Paragraph IV certification

is granted 180 days of exclusivity to market the drug. 21 U.S.C. § 355(j)(5)(B)(iv).

B. Factual Background

This case concerns Teva's prescription asthma treatment products, known as QVAR and QVAR Redihaler. Those products contain beclomethasone dipropionate, a corticosteroid, as well as a hydrofluoroalkane ("HFA"), an aerosol propellant. Teva acquired the rights to QVAR in 2006.

The complaint alleges that beginning in 2014, the year before the last patent claiming beclomethasone dipropionate was to expire, Teva began a multifaceted scheme to delay generic competition to QVAR for as long as possible. The scheme purportedly has four components: 1) product hops, 2) improper Orange Book listings, 3) a reverse payment and 4) sham litigation.

In the pharmaceutical context, a "product hop" is an introduction and transition to a new drug product. A product hop may take the form of a "soft switch," which generally is deemed to be legal for antitrust purposes or a "hard switch," which is not. See In Re Asacol Antitrust Litigation, 233 F. Supp. 3d at 269.

An alleged hard switch may be impermissibly coercive due to the operation of state substitution laws. Such laws

> permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug

unless a prescribing physician directs the pharmacist to dispense the prescription as written. Namenda, 787 F.3d 638 at 645. Substitution laws exist in all 50 states, id. at 644, but in most states, substitution is permitted, only if two drugs are both biologically and therapeutically equivalent. Id. Therapeutic equivalence typically requires that the two drugs have the same active ingredients, dosage form, strength and routes of administration. Id.

A "hard switch" product hop occurs when a manufacturer removes a brand drug from the market just prior to patent expiration, thus forcing consumers to switch onto a new drug product before the generic entry. The hard switch thus "deprive[s] potential generic manufacturers a prescription base for their generic version of the now-removed drug." In Re Asacol Antitrust Litigation, 233 F. Supp. 3d at 256 (citing Namenda, 787 F.3d at 648). When a generic drug comes to market after a hard switch, the brand drug cannot be automatically substituted for the generic at the pharmacy counter.

By contrast, a "soft switch" involves the introduction of a new product but the original product is left on the market prior to the generic entry. See Namenda, 787 F.3d at 654-55. Thus, consumer choice is left intact as well as a base of patients for whom a newly approved generic can automatically be switched.

According to the complaint, in 2003, the FDA issued guidance requiring all new, metered-dose inhaler products to include a dose counter. The guidance, however, purportedly exempted inhalers already in the market, such as QVAR. Nonetheless, in January, 2014, Teva filed a supplemental NDA to add a dose counter to QVAR, which was approved in May, 2014. Teva then, purportedly, discontinued its inhaler without the dose counter in what plaintiffs characterize as an initial "hard switch product hop."

The complaint further alleges that Teva made a second "hard switch" product hop when, in August, 2017, it obtained FDA approval for QVAR Redihaler and discontinued all QVAR sales. Unlike QVAR, QVAR Redihaler dispenses the drug when a user inhales.

Plaintiffs also allege that defendants have improperly listed patents in the Orange Book. As mentioned above, the Orange Book is supposed to list only patents of "the drug substance, drug product...[or] methods of using the drug for which it is listed." In re Lantus Direct Purchaser Antitrust

Litig., 950 F.3d at 4 (internal quotations omitted). Plaintiffs claim that Teva has improperly listed device-only patents in the Orange Book to deter would-be competitors from launching a generic version of QVAR.

The third component of the purported monopolization scheme involves an alleged reverse payment or "pay-for-delay" deal. Plaintiffs allege that in January, 2020, Amneal Pharmaceuticals ("Amneal") filed the first application for a generic version of QVAR. Teva did not sue Amneal but by the end of 2020, plaintiffs claim that Amneal "fell silent" on its plans to secure approval for the generic. From those circumstances, plaintiffs contend on information and belief that Teva agreed to pay Amneal to delay launching a generic version of QVAR.

The final component of the alleged scheme is "sham litigation." In 2020, two other generic manufacturers, Cipla Ltd. ("Cipla") and Aurobindo Pharma Ltd. ("Aurobindo"), filed ANDAs seeking approval for generic versions of QVAR which contained paragraph IV certifications. Teva promptly filed suit against both manufacturers thereby triggering a 30-month stay of FDA approval pursuant to the Hatch-Waxman Act. After stipulated dismissals of several claims, Teva ultimately settled with Aurobindo in December, 2022, and prevailed on its remaining claims against Cipla in June, 2023.

Plaintiffs filed a massive amended complaint in September, 2023, containing ten claims for relief, a claim for injunctive relief under Section 2 of the Sherman Act, 15 U.S.C. § 2, a plethora of claims under state antitrust and consumer protection statutes and a claim for unjust enrichment. Defendants have moved to dismiss the complaint in its entirety.

II. Motion to Dismiss

A. Legal Standard

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the subject pleading must contain sufficient factual matter to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011).

When rendering such a determination, a court may consider certain categories of documents extrinsic to the complaint "without converting a motion to dismiss into a motion for summary judgment." Freeman v. Town of Hudson, 714 F.3d 29, 36 (1st Cir. 2013) (citing Watterson v. Page, 987 F.2d 1, 3 (1st

Cir. 1993)). For instance, a court may consider documents of undisputed authenticity, official public records, documents central to a plaintiff's claim and documents that were sufficiently referred to in the complaint. Watterson, 987 F.2d at 3.

A court may not disregard properly pled factual allegations in the complaint even if actual proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12. Rather, the court's inquiry must focus on the reasonableness of the inference of liability that plaintiff is asking the court to draw. Id. at 13.

B. Analysis

The complaint alleges that Teva engaged in a monopolistic scheme with four components of illegal activity under federal and state antitrust laws: 1) two product hops, 2) the listing of inhaler devices in the Orange Book, 3) a pay-for-delay deal with Amneal and 4) sham litigation against Cipla and Aurobindo. The parties dispute the extent to which the merits of those individual allegations should be independently assessed for plausibility or be considered as component parts of an overall monopolistic scheme.

The Court will take the middle ground. On one hand, the plaintiffs

> should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.

In Re Asacol Antitrust Litigation, 233 F. Supp. 3d 247, 261 (D. Mass. 2017) (quoting Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 698–99 (1962)). Still, the Court can evaluate "the specific claims while ruminat[ing] upon the effect of combining those claims." Id. (quoting City of Anaheim v. S. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) (internal quotations omitted). Accordingly, the Court will assess each of the alleged component parts of the scheme while bearing in mind their synergistic effect.

1. Causation

The Court will first address antitrust law standing. Under sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, private parties may bring a cause of action for violation of federal antitrust law. To bring suit, however, plaintiffs must demonstrate that they have "antitrust standing." See Vazquez-Ramos v. Triple-S Salud, Inc., 55 F.4th 286, 293 (1st Cir. 2022). To establish antitrust standing, courts balance six factors:

> (1) the causal connection between the alleged antitrust violation and harm to the plaintiff; (2) an

> improper motive; (3) the nature of the plaintiff's alleged injury and whether the injury was of a type that Congress sought to redress with the antitrust laws ("antitrust injury"); (4) the directness with which the alleged market restraint caused the asserted injury; (5) the speculative nature of the damages; and (6) the risk of duplicative recovery or complex apportionment of damages.

RSA Media, Inc. v. AK Media Grp., Inc., 260 F.3d 10, 14 (1st Cir. 2001) (quoting Serpa Corp. v. McWane, Inc., 199 F.3d 6, 10 (1st Cir. 1999)). The causation requirement is emphasized and is the basis of defendant's challenge to the antitrust standing of plaintiffs.

Teva contends that even if the allegations of a scheme to block generic competition are proven, its

> '289, '587, and '808 patent [have been found] not invalid...and lawfully extend Teva's monopoly on QVAR products through 2032.

See Teva Branded Pharma. Prod. R&D, Inc. v. Cipla Ltd., 678 F.Supp.3d 559 (D.N.J. 2023). Accordingly, it asserts that the allegations could not have caused an antitrust injury because generic QVAR competition is legally precluded until 2032.

Plaintiffs rejoin that Teva's judgment in the Cipla litigation does not imply that all would-be competitors are necessarily barred from launching a generic competitor to QVAR. The Court agrees. According to the complaint, none of the claims of the '808, '587 or '289 patents that were the subject of the Cipla litigation relate to beclomethasone dipropionate,

the active ingredient in QVAR. Rather, the complaint avers that those patent claims relate to dose counters.

At this juncture, the Court has no basis for determining whether it would have been feasible to design an inhaler product that conforms to the ANDA process without infringing on Teva's dose-counter patents. Without more, Teva's judgment in the Cipla litigation does not preclude the possibility that no generic manufacturer would be able to design a generic QVAR product around Teva's patents.

Furthermore, the complaint alleges that Teva did not sue Amneal when that company sought to introduce a generic QVAR into the market and filed a paragraph IV certification concerning four of Teva's device-related patents in 2021. Teva has a strong incentive to defend its QVAR patents, so its decision to demur from suing Amneal adds credence to plaintiff's contention that a generic manufacturer could successfully design around Teva's QVAR patents. Accordingly, dismissal for want of antitrust standing is unwarranted.

2. Product Hops

Plaintiffs allege, as part of their federal and state claims of monopolization (Counts I, V and X) that defendants orchestrated two hard switch product hops to deter generic competition to QVAR.

The First Circuit has yet to rule on the antitrust ramifications of "soft switch" and "hard switch" product hops. This Court agrees, however, with another session of this Court that a so-called "soft switch" is not anti-competitive because it preserves consumer choice whereas a "hard switch" is anti-competitive because it forces adoption of the new iteration of the drug before generics have the chance to compete. See In re Asacol Antitrust Litig., 233 F. Supp. 3d at 269; see also Namenda, 787 F.3d at 654-55. Transaction costs and default positions can powerfully dissuade generic competitors that enter the market after a hard switch product hop.

Defendants contend that the complaint fails to allege an initial hard switch product hop from QVAR to QVAR with a dose counter. While the complaint lacks specificity, it clearly refers to that product hop in the First Claim for Relief. See Complaint ¶ 619.

Defendants also move to dismiss claims premised on a product hop from QVAR (with a dose counter) to QVAR Redihaler. They assert that the complaint admits that the transition to QVAR Redihaler was a permissible "soft switch." They emphasize that the complaint states that 1) the FDA allowed QVAR to remain listed on the "Discontinued Drug Product List" in the Orange Book and that the FDA would review QVAR ANDAs and 2) generic

competitors to QVAR "could be automatically substituted for prescriptions written for just QVAR, instead of QVAR Redihaler."

Defendants' contention is unavailing. Because no generic QVAR existed at the time Teva purportedly discontinued QVAR in favor of QVAR Redihaler, asthma patients necessarily had to be transitioned onto QVAR Redihaler. The complaint states that future generic QVAR prescriptions could be automatically substituted for QVAR prescriptions but not that generic QVAR could be switched for QVAR Redihaler prescriptions or that both QVAR and QVAR Redihaler remained on the market contemporaneously for any significant period of time. Compare In re Asacol Antitrust Litig., 233 F. Supp. 3d at 269 (dismissing product hop claim where "both products remained on the market contemporaneously for four years.").

Ultimately, the debate is academic. There are no standalone product hop claims. To the extent defendants seek to dismiss on the grounds of defective claims of products hops, their motion will be denied.

3. Reverse Payment

Defendants move to dismiss plaintiffs' claims arising from a purported reverse payment deal between Teva and Amneal (including Counts III and VII and the reverse payment components of the state and federal monopolization scheme).

In a reverse payment, a brand drug manufacturer agrees to pay a potential generic competitor to delay bringing a generic drug to market. The payment is subject to antitrust scrutiny under the rule of reason. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 551 (1st Cir. 2016). Under that analysis, courts look to

> its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

Id. (quoting FTC v. Actavis, Inc., 570 U.S. 136, 159 (2013). The First Circuit has rejected the requirement of exact figures and calculations at the pleading stage and instead, requires plaintiffs

> [to] allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment.

In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552.

Here, Teva asserts that the very existence of a reverse payment is pure conjecture and, in any event, plaintiffs have failed to allege facts supporting a "large and unjustified" reverse payment.

Plaintiffs acknowledge that as of yet, they have no proof of the purported reverse payment because 1) any agreement between Teva and Amneal would have been resolved prior to the commencement of litigation and 2) any settlement would not

therefore be part of the public record. Still, they contend that the facts surrounding Amneal's announcement of a generic QVAR and subsequent, unexplained failure to launch the drug conjures a sufficient inference of a reverse payment. They point out that Amneal's failure to launch a generic was "possibly" worth hundreds of millions of dollars, given the 180 days of exclusivity it would have had as the first generic QVAR ANDA filer.

The Court agrees that plaintiffs have pled sufficient facts to avoid dismissal of their claim of a reverse payment. They allege that in 2020, Amneal became the first drug manufacturer to file an ANDA for a generic QVAR. Accordingly, Amneal's ANDA presented a considerable financial opportunity for it and, conversely, a loss for Teva, which, in its briefing, insists it maintains exclusivity over QVAR until 2032. Given those dynamics, plaintiffs plausibly allege that Teva's surprising decision not to sue Amneal within 45 days of receiving the ANDA can be explained only by an out-of-court settlement. Adding credence to that inference are facts from the complaint describing how Amneal hedged representations of a generic QVAR launch in late 2020 and eventually fell silent about future plans to bring generic QVAR to market. Such allegations sufficiently describe "the general contours of when an agreement was made...with a context that tends to make said agreement

plausible." Evergreen Partnering Grp., Inc. v. Pactiv Corp., 720 F.3d 33, 46 (1st Cir. 2013).

As to the substance of the agreement, plaintiffs sufficiently plead facts that the hypothesized reverse payment was "large and unjustified." In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552. As plaintiffs point out, it is well-established that ANDA first filers have considerable financial incentive to bring generics to market. Indeed, the exclusivity period "potentially worth millions of dollars, is meant to incentivize generic pharmaceutical companies to bear the costs of the patent infringement lawsuit." Mylan Pharm., Inc. v. FDA, 594 Fed. App'x 791, 794 (4th Cir. 2014) (citing Teva Pharm., USA, Inc. v. Leavitt, 548 F.3d 103, 104 (D.C. Cir. 2008)). Plaintiffs plausibly infer that any reverse payment here would have had to be substantial. The antitrust harm in a reverse-payment is that it "seeks to prevent the risk of competition." Actavis, Inc., 570 U.S. at 157. Given the continued lack of generic QVAR competition since Amneal filed its ANDA more than four years ago and the allegations of selective dismissals in the Cipla ANDA litigation concerning a patent claim relevant to Amneal, plaintiffs have sufficiently alleged an unjustified reverse payment. While the complaint lacks details, it is understood that proof of such allegations

> require evidence in the exclusive possession of the defendants, as well as expert analysis.

In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 244 (D. Conn. 2015). Here, with the benefit of discovery, the particulars can be best evaluated at summary judgment.

4. Sham Litigation

Plaintiffs allege that Teva violated state antitrust law and consumer protection laws (Counts IV and VIII, respectively) by commencing sham litigation against Cipla and Aurobindo. Teva filed suit against those entities in 2020 after they filed Paragraph IV certifications to introduce generic competitors to QVAR. The suits were consolidated in 2021. After the stipulated dismissal of certain claims, Teva prevailed against Cipla and settled with Aurobindo.

A party petitioning the government for redress is "generally immune from antitrust liability." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993). That immunity extends to citizens or groups who petition the legislature, the executive, administrative agencies or the courts. Cali. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510–11 (1972). It does not, however, cover "sham" activities or lawsuits because

> application of the Sherman Act would be justified when petitioning activity, ostensibly directed toward influencing governmental action, is a mere sham to cover an

> attempt to interfere directly with the business relationships of a competitor.

Prof'l Real Estate Investors, 508 U.S. at 56 (quoting Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)) (internal quotations omitted).

To determine whether litigation is a sham, courts look to whether the suit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. at 60. If, however, an "objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome" the sham litigation claim will fail. Id.

If the Court concludes that the suit was objectively baseless, it considers the subjective motivations of the alleged monopolist. United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp., 902 F.3d 1, 13 (1st Cir. 2018) (internal quotations omitted). In particular, the Court determines if a litigant is motivated by an attempt to interfere directly with "the business relationships of a competitor...as an anticompetitive weapon." Prof'l Real Estate Investors, 508 U.S. at 60-61 (internal quotations omitted).

Critically, "[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." See Nuance Commc'ns, Inc. v. Omilia Nat. Language Sols., Ltd., No. CV 19-11438-PBS, 2020 WL 2198362, at *8 (D. Mass. May

6, 2020) (quoting Prof'l Real Estate Investors, 508 U.S. at 60 n.5).

Here, Teva contends that because it won the ANDA suit against Cipla, the litigation was not a sham as a matter of law. Plaintiffs rejoin that Teva's patents asserted against Cipla and Aurobindo were improperly included in the Orange Book, and that, therefore, Teva lacked standing to assert those patents until after a generic product was introduced. Plaintiffs add that during the litigation, Teva selectively dismissed claims with respect to certain patents but refused to stipulate to their non-infringement. Plaintiffs contend that Teva sought to prevent adjudication of patent claims that otherwise blocked Amneal from introducing its generic version of QVAR.

Teva's success in the Cipla ANDA litigation forecloses the claims of sham litigation. In June, 2023, following a three-day bench trial, District Judge Julien X. Neals of the District of New Jersey found that Cipla's ANDA product infringed the asserted '289, '587, and '808 patents and the asserted patents were not invalid for obviousness. Teva Branded Pharm. Prod. R&D, Inc. v. Cipla Ltd., 678 F. Supp. 3d at 563. This Court is unaware of any cases in which a winning lawsuit has been deemed sham litigation. See Prof'l Real Estate Investors, 508 U.S. at 60 n.5; see also U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 597 (Fed. Cir. 1995).

Dismissing plaintiffs' sham litigation claims does not "impermissibly excise" them from the overall monopolization scheme. See In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 261 (D. Mass. 2017). The Court must assess "specific claims while ruminating upon the effect of combining those claims." Id. The mere accusation of a sham is insufficient but the selective stipulation and dismissal of claims in the Cipla litigation is pertinent to the pay-for-delay and overall monopolization scheme and is not negated by Teva's ultimate victory.

Teva's success forecloses the sham litigation claim, but not this Court's scrutiny of its conduct during the Cipla litigation. Accordingly, the scope of discovery in this case may include Teva's selective dismissal of claims as to the '509, '510 and '512 patents in the Cipla litigation which is relevant to the monopolization scheme and the purported existence of a reverse payment agreement. Counts IV and VIII will be dismissed.

5. Unjust Enrichment

Defendants contends that the claim for unjust enrichment (Count IX) should be dismissed because 1) the complaint fails to allege sufficiently unlawful conduct and 2) plaintiffs fail to identify the relevant state laws at issue.

As to Teva's first contention, as discussed supra, plaintiffs have sufficiently alleged unlawful conduct with

respect to some of their claims. Furthermore, the Court will not require at this stage more specificity in the claim for unjust enrichment than plaintiffs' allegations of violations of "the common law of all fifty states and commonwealths." As another session of this Court has noted, "there are only a few differences in the description of unjust enrichment claims as between states." Overka v. Am. Airlines, Inc., 265 F.R.D. 14, 21 (D. Mass. 2010). Accordingly, plaintiffs have sufficiently alleged a claim for unjust enrichment by citing to the common law of the 50 states.

6. Sherman Act

Defendants contend that the Sherman Act claim (Count X) should be dismissed because it is dependent upon the deficient factual claims in the complaint. Because the Court has found that the complaint has alleged the plausible components of a monopolization scheme, the motion to dismiss Count X will be denied.

7. Remaining State Law Defenses

Teva concludes its brief with a litany of defenses to the state law claims, i.e. that 1) they fail by virtue of deficiencies in the federal claims, 2) plaintiffs lack standing in the 20 states where they or their members do not reside, 3) the District of Columbia, Massachusetts and Mississippi claims fail due to insufficient contacts with those jurisdictions,

4) the state unilateral monopolization claims fail under California, Kansas, New York and Tennessee law, 5) the consumer protection claims fail to meet the pleading standard, 6) the consumer protection claims for six states do not cover antitrust matters and 7) plaintiffs fail to plead deception under the consumer protection acts of nine states. The Court will address each defense in turn.

i. Deficiencies in the federal claims

First, there is no merit to the assertion that the state law claims fail by virtue of supposed deficiencies in the federal claims. As discussed, plaintiffs have sufficiently pled a Sherman Act claim and generally allege a plausible monopolization scheme.

ii. Standing

Defendants assert that the representative plaintiffs lack standing to pursue the state law claims for the 20 states in which they do not reside or have financial dealings with respect to QVAR. To assess standing for a putative class action asserting aggregate harms, the court focuses on whether the differences that exist between class representatives and members are such that leave the representatives without a sufficient personal stake in the litigation. See In re Asacol Antitrust Litig., 907 F.3d 42, 49 (1st Cir. 2018). This circuit has required only that "a plaintiff make a single purchase in order

to satisfy standing for a claim brought under multiple state laws." Id. at 50 (citing Nexium, 777 F.3d at 31-32).

Defendants contend that differences in state law leave plaintiffs with an insufficient stake in the litigation but the Court disagrees. As discussed infra, certain states have minor variations in the requirements for certain antitrust and consumer protection claims. Those differences are insufficient to render the several, geographically diverse plaintiffs without a stake in this case. Generally, "success on the claim under one state's law will more or less dictate success under another state's law" in the matter. Id. at 49.

iii. State Antitrust Claims: Intrastate conduct

Defendants assert that the Massachusetts, District of Columbia and Mississippi claims fail because none of the alleged anticompetitive activity occurred in those jurisdictions.

It is unconstitutional under the Commerce Clause of the United States Constitution to apply District of Columbia Code antitrust provisions to interstate conduct. The D.C. Code requires a "sufficient nexus" to the jurisdiction for an antitrust claim to proceed. See Sun Dun, Inc. of Wash v. Coca-Cola Co., 740 F. Supp. 381, 396 (D. Md. 1990). At this stage of the litigation it is unclear whether any claim sufficiently satisfies that nexus.

Mississippi's Antitrust Act requires "at least some conduct" that is wholly intrastate. In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig., 383 F. Supp. 3d 187, 267 (S.D.N.Y. 2019). The dispositive factor is the physical location of the conduct. Id. at 266. The complaint does not plausibly allege any anticompetitive conduct of defendants in Mississippi. Counts I-IV will be dismissed as to the Mississippi cause of action.

Finally, with respect to Massachusetts, the parties dispute under which section of M.G.L. ch. 93A the claims are made. Section 9 of that statute provides a cause of action for individual consumers who have suffered a loss due to an unfair trade practice whereas section 11 pertains to persons acting in a business context. See In re Pharmaceutical Industry Average Wholesale Price Litig., 582 F.3d 156, 191 (1st Cir. 2009). Unlike actions pursuant to section 9, section 11 claims must concern conduct that occurred "primarily and substantially" within the Commonwealth. Fishman Transducers, Inc. v. Paul, 684 F.3d 187, 197 (1st Cir. 2012). Where, as here, the impact of the alleged conduct is on consumers nationwide, the "primarily" component is not satisfied. Id. Therefore, to the extent plaintiffs' claims are brought under section 11, they will be dismissed.

iv. State Antitrust Claims: Conspiracy requirements

Defendants assert that Counts I-IV fail under the California, New York, Kansas and Tennessee antitrust laws because those laws require a conspiracy involving two or more entities. Plaintiffs respond that its reverse payment allegations involve joint monopolization conduct between Teva and Amneal. As discussed supra, Count IV will be dismissed with respect to all causes of action.

Defendants are correct that the antitrust statutes in the four subject jurisdictions require joint conduct. Plaintiffs sufficiently allege joint conduct by virtue of the reverse payment with respect to Count I (total monopolization scheme) and Count III (specifically concerning the alleged reverse payment). There is no joint conduct alleged in Count II, however, which concerns allegations of improper Orange Book listings. Accordingly, that claim will be dismissed with respect to the California, New York, Kansas and Tennessee causes of action.

v. Consumer protection claims: Pleading Standard

Defendants contend that the consumer protection act claims (Counts V-VIII) are threadbare and are insufficient under Fed. R. Civ. P. 8. In those claims, plaintiffs incorporate and reallege the facts of the preceding 600+ paragraphs. The

allegations describing a complex, multi-step monopolization scheme state plausible consumer protection violations. It is unnecessary and indeed would be impractical to require additional allegations tailored to each of the many state consumer protection acts cited.

vi. Consumer protection claims: extension to the antitrust context

Defendants also pursue a more targeted response to the consumer protection claims and seek to dismiss the causes of action in six states where the consumer protection laws purportedly do not extend to antitrust conduct (Arkansas, Illinois, New Mexico, Utah, South Dakota and Virginia).

Arkansas. With respect to Arkansas's consumer protection statute, the Arkansas Supreme Court has held that its proscription of "unconscionable" trade practices is broad and that the statute is to be liberally construed. See, e.g., In re Packaged Seafood Prods. Antitrust Litig., 242 F. Supp. 3d 1033, 1072 (S.D. Cal. 2017). The statute also provides, however, that a

> private class action under this subsection is prohibited unless the claim is being asserted for a violation of Arkansas Constitution, Amendment 89.

Ark. Code Ann. § 4-88-113(f)(1)(A)-(B). Here, there is no contention that the alleged conduct violates Amendment 89 of the Arkansas Constitution. Plaintiff has not cited nor has this

Court found precedent from the Arkansas courts extending the act to antitrust actions. Accordingly, the Arkansas consumer protection claim is not viable. See In re HIV Antitrust Litig., 2022 WL 22609107, at *17 (N.D. Ca. Sep. 27, 2022).

Illinois. Under the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 Ill. Comp. Stat. § 505/1 et seq., the Illinois Supreme Court does not permit an antitrust claim where the "the legislature had declined to include such a cause of action under the Illinois Antitrust Act." In re Flonase Antitrust Litig., 692 F.Supp.2d 524, 538 (E.D. Pa. 2010). Neither party has addressed whether the antitrust claims at issue are actionable under the Illinois Antitrust Act. Accordingly, the motion to dismiss with respect to the ICFA will be denied but may be revisited at the summary judgment stage.

New Mexico. The Court disagrees with defendants that the New Mexico Unfair Practices Act ("NMUPA") does not cover antitrust conduct. That statute proscribes "unconscionable trade practice[s]" including acts that result in a "gross disparity between the value received by a person and the price paid." N.M. Stat. Ann. § 57-12-2(D). It is plausible that such disparities may arise in an antitrust context where the pricing power of an alleged monopolist deprives consumers of the opportunity to purchase a product for its fair market value. See also Sergeants Benevolent Ass'n Health & Welfare Fund v.

Actavis, plc, 2018 WL 7197233, at * 47-48 (S.D.N.Y. Dec. 26, 2018).

Utah. Utah's consumer protection statute, the Utah Consumer Sales Practices Act ("UCSPA"), Utah Code Ann. § 13-11-4, is modelled after the FTC Act. See Utah Code Ann. § 13-11-2(4). It does not, however, include a provision that is analogous to the FTC Act's proscription of "unfair competition." See 15 U.S.C. § 45. In the absence of any rulings from the Utah state courts on the application of UCSPA in the antitrust context, this Court will decline to extend its scope and will dismiss the Utah consumer protection claims.

South Dakota and Virginia. With respect to the consumer protection statutes of Virginia and South Dakota, defendants contend that they apply only to specific, listed conduct that does not include antitrust violations.

Under the South Dakota deceptive trade practices law, proof of a purposeful "misrepresentation or concealment of a fact on which plaintiff relied and that caused an injury to plaintiff" is required to state a claim. Nw. Pub. Serv., a Div. of Nw. Corp. v. Union Carbide Corp., 236 F.Supp.2d 966, 973-74 (D.S.D. 2002). That requirement does not, however, preclude pleading an antitrust claim under the statute. See, e.g., In re DDAVP Indirect Purchaser Antitrust Litig. v. Ferring Pharms. Inc., 903 F. Supp. 2d 198 (S.D.N.Y. 2012).

Virginia's consumer protection statute also requires fraud or misrepresentation to state a claim thereunder, see In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 760 (E.D. Pa. 2014), but does not preclude antitrust claims. See In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 703 (E.D. Pa. 2014). The claims under the South Dakota and Virginia consumer protection statutes will not be dismissed.

vii. Consumer protection claims: failure to allege deception

Finally, defendants assert that the complaint does not allege deception so as to be actionable under the consumer protection statutes of Arkansas, California, Illinois, Maine, Nevada, New York, South Dakota, Utah and Virginia.

The Court declines to consider these defenses state-by-state because the surviving allegations sufficiently allege "deception directed at the consumer, or deceptive acts in connection with the sale of goods." The alleged improper Orange Book listings can be construed as misrepresentations because Teva had to certify that each patent claimed only "the drug substance, drug product (composition / formulation), or one or more methods of using the drug for which it is listed." In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d at 4 (internal quotations omitted); see also 21 C.F.R. §

314.5(c)(2)(i). Here, plaintiffs allege that Teva listed several device-only patents that do not claim the drug in the Orange Book which, if proven, would contradict Teva's certification. Furthermore, the alleged hard-switch product hops are plausibly deceptive because they required consumers to switch to new iterations of drug products at the expense of potential generic substitution.

ORDER

For the foregoing reasons, the motion of defendants, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. is, with respect to Counts IV and VIII in their entirety, Counts I-IV as to the Mississippi cause of action and M.G.L. ch. 93A, § 11, Count II as to the California, New York, Kansas and Tennessee causes of action and Counts V-VIII as to the Arkansas and Utah causes of action, **ALLOWED**, but is otherwise **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated: May 7, 2024